

EFFECTIVE JULY 1, 2023 J-CODE  
FOR PANZYGA NOW AVAILABLE

panzyga®

Immune Globulin  
Intravenous (Human) - ifas  
10% Liquid Preparation

# Billing and Coding Information

## INDICATIONS AND USAGE

PANZYGA (Immune Globulin Intravenous [Human] - ifas) is indicated for the treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older; this includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies; chronic immune thrombocytopenia (cITP) in adults to raise platelet counts to control or prevent bleeding; and chronic inflammatory demyelinating polyneuropathy (CIDP) in adults to improve neuromuscular disability and impairment.

## SELECTED SAFETY INFORMATION

### WARNING: THROMBOSIS, RENAL DYSFUNCTION, AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including PANZYGA. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IGIV products, including PANZYGA. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PANZYGA does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer PANZYGA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. [see *Full Prescribing Information, Warnings and Precautions (5.2, 5.4)*]

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for PANZYGA. Coding and coverage policies change periodically and often without warning. The codes shown here are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use.

The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided in this document should not be considered a guarantee of coverage or reimbursement for PANZYGA.

Please see Important Safety Information on pages 10-11 and [click here](#) for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

Pfizeriguide™

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Please see Important Safety Information on pages 10-11 and [click here](#) for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

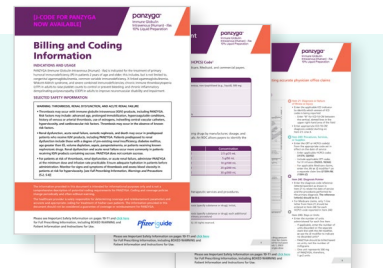
# Introduction and Pfizer IGuide™ Hub

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For your patient claim submissions for PANZYGA, Pfizer is committed to providing billing and coding information for the following FDA-approved indications:

- 1 Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
- 2 Primary humoral immunodeficiency (PI) in patients 2 years of age and older
- 3 Chronic immune thrombocytopenia (cITP) in adults

We have developed this guide to provide you with general coding information and claims submission details for PANZYGA.



## Pfizer IGuide™

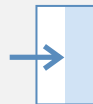
When you've decided PANZYGA is appropriate for your patient, Pfizer IGuide™ may help.

Enroll your patients in Pfizer IGuide™ for support

The Pfizer IGuide™ team can:



Conduct a benefits verification to determine your patient's coverage for PANZYGA including out-of-pocket costs



Determine payer requirements and provide information about the prior authorization process and appeals process as needed\*



Enroll eligible patients within the PANZYGA Co-Pay Program†

For additional information, [click here](#) to visit the Pfizer IGuide™ website

If you have any questions or need additional assistance, please call Pfizer IGuide™ at 1-844-448-4337, 8 AM to 8 PM ET, Monday through Friday

\*Please note where a PA is required, the physician must submit required information directly to the patient's insurer.

†Terms and conditions apply. Patients must be 2 years or older to be eligible. Patients must have commercial insurance to be eligible. Patients are not eligible if they are enrolled in a state or federal insurance program. [Click here](#) for full Terms and Conditions.

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# Coding and Reimbursement for PANZYGA

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This section describes the types of codes that are likely to be most relevant to claims for PANZYGA. PANZYGA is a solution for infusion to be administered intravenously (IV) in an infusion center, physician’s office, or at home by a trained healthcare provider.

## International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes<sup>1</sup>

ICD-10-CM diagnosis codes are used for identifying and documenting a patient’s specific diagnosis. These codes are used by all healthcare providers, and are recognized by all insurers. Local coverage determinations and articles should be consulted for additional covered indications.

<b>D69</b>	<b>Purpura and other hemorrhagic conditions</b>
D69.3	Immune thrombocytopenia purpura Hemorrhagic (thrombocytopenic) purpura Idiopathic thrombocytopenic purpura Tidal platelet dysgenesis
<b>D80</b>	<b>Immunodeficiency with predominantly antibody defects</b>
D80.0*	Hereditary hypogammaglobulinemia Autosomal recessive agammaglobulinemia (Swiss type) X-linked agammaglobulinemia [Bruton] (with growth hormone deficiency)
D80.1	Nonfamilial hypogammaglobulinemia Agammaglobulinemia with immunoglobulin-bearing B-lymphocytes Common variable agammaglobulinemia [CVAgamma] Hypogammaglobulinemia NOS
D80.2*	Selective deficiency of immunoglobulin A [IgA]
D80.3*	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4*	Selective deficiency of immunoglobulin M [IgM]
D80.5*	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6*	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7*	Transient hypogammaglobulinemia of infancy
D80.8	Other immunodeficiencies with predominantly antibody defects Kappa light chain deficiency
D80.9	Immunodeficiency with predominantly antibody defects, unspecified
<b>D81</b>	<b>Combined immunodeficiencies</b>
D81.0*	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1*	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2*	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.4	Nezelof’s syndrome

Table continues on the next page.

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# Coding and Reimbursement for PANZYGA (continued)

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<b>D81 Combined immunodeficiencies (continued)</b>	
D81.5*	Purine nucleoside phosphorylase [PNP] deficiency
D81.6*	Major histocompatibility complex class I deficiency <i>Bare lymphocyte syndrome</i>
D81.7*	Major histocompatibility complex class II deficiency
D81.82*	Activated Phosphoinositide 3-kinase Delta Syndrome [APDS]
D81.89*	Other combined immunodeficiencies
D81.9*	Combined immunodeficiencies, unspecified <i>Severe combined immunodeficiency disorder [SCID] NOS</i>
<b>D82 Immunodeficiency associated with major other defects</b>	
D82.0*	Wiskott-Aldrich syndrome <i>Immunodeficiency with thrombocytopenia and eczema</i>
D82.1*	Di George's syndrome <i>Pharyngeal pouch syndrome</i> <i>Thymic aplasia or hypoplasia</i> <i>Thymic aplasia or hypoplasia with immunodeficiency</i>
D82.2	Immunodeficiency with short-limbed stature
D82.3	Immunodeficiency following hereditary defective response to Epstein-Barr virus <i>X-linked lymphoproliferative disease</i>
D82.4*	Hyperimmunoglobulin E [IgE] syndrome
D82.8	Immunodeficiency associated with other specified major defects
D82.9	Immunodeficiency associated with major defect, unspecified
<b>D83 Common variable immunodeficiency</b>	
D83.0*	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1*	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2*	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8*	Other common variable immunodeficiencies
D83.9*	Common variable immunodeficiency, unspecified
<b>D84 Other immunodeficiencies</b>	
D84.9	Immunodeficiency, unspecified <i>Immunocompromised NOS</i> <i>Immunodeficient NOS</i> <i>Immunosuppressed NOS</i>
<b>G11 Hereditary ataxia</b>	
G11.3*	Cerebellar ataxia with defective DNA repair <i>Ataxia telangiectasia [Louis-Bar]</i>
<b>G61 Inflammatory polyneuropathy</b>	
G61.81	Chronic inflammatory demyelinating polyneuritis

\*Medicare Part B-approved diagnosis codes for treatment with PANZYGA in the home. All other diagnoses may qualify for coverage under Medicare Part D plans.<sup>2</sup>

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# Coding and Reimbursement for PANZYGA (continued)

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## Healthcare Common Procedure Coding System (HCPCS) Code<sup>3</sup>

HCPCS codes are used for billing drugs and services to Medicare, Medicaid, and commercial payers.

**Effective July 1, 2023, PANZYGA now has a permanent J-code, J1576.** For dates of service before July 1, 2023, use J1599 (Injection, immune globulin, intravenous, non-lyophilized [e.g., liquid], not otherwise specified, 500 mg).

Code	Description
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
Additional information required by most payers on claim forms:	<ul style="list-style-type: none"><li>• Branded/generic name</li><li>• Strength</li><li>• Dosage administered</li><li>• Route of administration</li><li>• National Drug Code (NDC)</li></ul>
Some payers may also request:	<ul style="list-style-type: none"><li>• Package insert</li><li>• Drug purchase invoice</li><li>• Documentation to support medical necessity</li></ul>

## PANZYGA National Drug Codes (NDCs)<sup>4</sup>

An NDC is a universal, unique, 3-segment number identifying drugs by manufacturer, dosage, and package size. NDCs are used for billing drugs and biologicals.

Billing NDC	Carton NDC	Concentration
00069-1109-01	00069-1109-02	2.5 g/25 mL
00069-1224-01	00069-1224-02	5 g/50 mL
00069-1312-01	00069-1312-02	10 g/100 mL
00069-1415-01	00069-1415-02	20 g/200 mL
00069-1558-01	00069-1558-02	30 g/300 mL

## Current Procedural Terminology (CPT®)\* Codes<sup>5</sup>

CPT codes describe the medical, surgical, diagnostic, and therapeutic services and procedures.

Code	Description
96365	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	IV infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour (list separately in addition to code for primary procedure)

\*CPT is a registered trademark of the American Medical Association (AMA). All rights reserved.

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# Coding and Reimbursement for PANZYGA (continued)

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## CODES FOR HOME INFUSION/SPECIALTY PHARMACIES

### Home Infusion Therapy<sup>3</sup>

HCPCS per diem S-codes are used by commercial payers and Medicaid to report drugs, services, and supplies. These codes are not payable by Medicare.

Code	Description
S9338	Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

### IVIg Demonstration<sup>3,6,7</sup>

The Medicare IVIg Demonstration provides a bundled payment under Medicare Part B for items and services that are necessary for the in-home administration of IVIg for the treatment of PI. J1599 (Injection, immune globulin, intravenous, non-lyophilized [eg, liquid], not otherwise specified, 500 mg) is covered under the demonstration and should be used for PANZYGA for dates of service prior to July 1, 2023. We expect that J1576 will be added to the list of Ig products in the demonstration for dates of service on or after July 1, 2023.

The demonstration has been extended through December 31, 2023.

Code	Description
Q2052	Services, supplies and accessories used in the home under the Medicare IVIg demonstration

Codes are subject to change.

Please see Important Safety Information on pages 10-11 and [click here](#) for Full Prescribing Information, including BOXED WARNING and Patient Information and Instructions for Use.

# Sample Claim Form

This section offers providers guidance in submitting accurate physician office claims for administration of PANZYGA.

## Sample Physician Office Claim Form (CMS-1500)

**HEALTH INSURANCE CLAIM FORM**  
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BK/LK LUNG OTHER  
 (Medicare#)  (Medicaid#)  (DD/ID/ID)  (Member EM)  (IDM)  (IDM)  (IDM)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)  
 3. PATIENT'S BIRTH DATE MM DD YY SEX M F  
 4. INSURED'S NAME (Last Name, First Name, Middle Initial)  
 5. PATIENT'S ADDRESS (No., Street)  
 6. PATIENT RELATIONSHIP TO INSURED  
 Self  Spouse  Child  Other   
 7. INSURED'S ADDRESS (No., Street)  
 8. RESERVED FOR NUCC USE  
 9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)  
 10. IS PATIENT'S CONDITION RELATED TO:  
 a. EMPLOYMENT? (Current or Previous) YES  NO   
 b. AUTO ACCIDENT? YES  NO  PLACE (State)  
 c. OTHER ACCIDENT? YES  NO   
 11. INSURED'S POLICY GROUP OR FECA NUMBER  
 a. INSURED'S DATE OF BIRTH MM DD YY SEX M F  
 b. RESERVED FOR NUCC USE  
 c. OTHER CLAIM ID (Designated by NUCC)  
 d. INSURANCE PLAN NAME OR PROGRAM NAME  
 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits, either to myself or to the party who accepts assignment below.  
 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below.  
 14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) QUAL. MM DD YY  
 15. OTHER DATE QUAL. MM DD YY  
 16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY  
 17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI  
 18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY  
 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)  
 20. OUTSIDE LAB? YES  NO  \$ CHARGES  
 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate #&L to service line below (24E)) ICD Ind. A. B. C. D. E. F. G. H. I. J. K. L.  
 22. RESUBMISSION CODE ORIGINAL REF. NO.  
 23. PRIOR AUTHORIZATION NUMBER  
 24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY B. PLACE OF SERVICE EMG C. PROCEDURES, SERVICES, OR SUPPLIES (Specify Unusual Circumstances) D. CPT/HCPCS MODIFIER E. REFERENCE LETTER F. \$ CHARGES G. UNIT PRICE H. I. ID. J. RENDERING PROVIDER ID. #  
 25. FEDERAL TAX ID. NUMBER SSN EIN 26. PATIENT'S ACCOUNT NO. 27. ACCEPT ASSIGNMENT? (For gov. claims, not used) YES  NO  28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rsvd for NUCC Use  
 31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED DATE a. NPI b. NPI  
 32. SERVICE FACILITY LOCATION INFORMATION 33. BILLING PROVIDER INFO & PH # ( )

### Item 21: Diagnosis or Nature of Illness or Injury

- Enter the applicable ICD indicator to identify which version of ICD codes is being reported
  - Enter "0" for ICD-10-CM between the vertical, dotted lines in the upper right-hand area of the field
- Enter appropriate ICD-10-CM diagnosis code(s) starting on Item 21, Line A

### Item 24D: Procedures, Services, or Supplies

- Enter the CPT or HCPCS code(s) from the appropriate code set in effect on the date of service
  - Enter applicable HCPCS codes (J1576, Q2052)
  - Include applicable CPT codes for IV infusion (96365, 96366)
  - For applicable Medicare claims, enter the JW or JZ modifier\* on a separate claim line (J1599-JW, J1599-JZ)

### Item 24E: Diagnosis Pointer

- Enter the diagnosis code reference letter(s) (pointer) as shown in Item 21 to relate the date of service and the procedures performed to the primary diagnosis. The reference letter(s) should be A-L
- For Medicare claims, only 1-line letter from Item 21 should be entered in Item 24E for each HCPCS code reported in Item 24D

### Item 24G: Days or Units

- Enter the number of units administered for each line item
  - If applicable, enter the number of units discarded on the separate claim line with the JW modifier, or use the JZ modifier to indicate no discarded units\*
  - PANZYGA should be billed based on units, not the number of milligrams
  - One unit represents 500 mg of PANZYGA, therefore, 1 g=2 units

\*JW – Drug amount discarded/not administered to any patient. JZ – Zero drug amount discarded/not administered to any patient. The JZ modifier will be effective for claims with dates of service on or after January 1, 2023, but will not be required for inclusion on claims until July 1, 2023. For claims with dates of service beginning July 1, 2023 or after, providers will be required to use the JZ modifier on claims for single-dose containers when there are no discarded amounts.<sup>3</sup>

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# PANZYGA Co-Pay Program

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## PANZYGA Co-Pay Assistance Is Available for Eligible Patients\*

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Eligible, commercially insured patients may reduce out-of-pocket costs by up to \$12,500 per year or the cost of a patient's co-pay in a 12-month period, whichever is less.

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\*Terms and conditions apply. Patients must be 2 years or older to be eligible. Patients must have commercial insurance to be eligible. Patients are not eligible if they are enrolled in a state or federal insurance program.

[Click here](#) for full Terms and Conditions.

If you have any questions about the available co-pay assistance through the PANZYGA Co-Pay Program, please call Pfizer IGuide™ at 1-844-448-4337, 8 AM to 8 PM ET, Monday through Friday.

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# Indications and Usage and Important Safety Information

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## IMPORTANT SAFETY INFORMATION

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- **Thrombosis may occur with immune globulin intravenous (IGIV) products, including PANZYGA. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling central vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.**
- **Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur in predisposed patients who receive IGIV products, including PANZYGA. Patients predisposed to renal dysfunction include those with a degree of pre-existing renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. PANZYGA does not contain sucrose.**
- **For patients at risk of thrombosis, renal dysfunction, or acute renal failure, administer PANZYGA at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. [see *Full Prescribing Information, Warnings and Precautions (5.2, 5.4)*]**

# Indications and Usage and Important Safety Information

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## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Contraindications

PANZYGA is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin and in IgA-deficient patients with antibodies against IgA and history of hypersensitivity.

### Warnings and Precautions

Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum osmolarity, and hyponatremia may occur in patients receiving PANZYGA.

Aseptic meningitis syndrome may occur in patients receiving PANZYGA, especially with high doses or rapid infusion.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to PANZYGA treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.

Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Monitor blood pressure prior to, during, and following PANZYGA infusion.

Carefully consider the relative risks and benefits before prescribing the high dose regimen (for cITP) in patients at increased risk of volume overload.

PANZYGA is made from human plasma and may contain infectious agents, e.g. viruses and theoretically, the Creutzfeldt-Jakob disease agent.

### Adverse Reactions

PI – The most common adverse reactions (>5% study subjects) were headache, nausea, fever, fatigue, and abdominal pain.

cITP in adults – The most common adverse reactions (>5% study subjects) were headache, fever, nausea, vomiting, dizziness, and anemia.

CIDP in adults – The most common adverse reactions (>5% study subjects) were headache, fever, dermatitis, and blood pressure increase.

The risk information provided here is not comprehensive; see full Prescribing Information and Boxed Warning for PANZYGA.

**You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (US only). If you prefer, you may contact the US Food and Drug Administration (FDA) directly. Visit [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.**

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# References

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1. National Center for Health Statistics. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM): 2023 Codes Tables and Index. Accessed February 28, 2023. <https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm>
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